

K200088 g.Estim FESOct 29, 2020
288 days to decisionK200088 · Product code: **IPF** · Physical Medicine
Source: <https://www.510kdatabase.net/k200088/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered (IPF)
Date received	Jan 15, 2020
Decision date	Oct 29, 2020
Days to decision	288 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	G.Tec Medical Engineering GmbH
Location	Schiedlberg, AT
Contact	Christoph Guger
510(k) history	6 submissions · 6 cleared · 2006-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k200088/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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